

## REMARKS

Claims 38-42 and 44-54 are pending in the application. Claims 39-41, 44, 45, 53 and 54 have been allowed. Claims 38, 42, and 46-50 have been amended. Claims 51 and 52 have been canceled. Support for the claim amendments may be found throughout the application as filed, including, but not limited to, paragraphs 7, 8, 9, 56 and 81.

In view of the following remarks, reconsideration and withdrawal of the rejections to the application in the Office Action is respectfully requested.

### *I. Claim Objections and Correction to the Specification*

The Examiner has objected to Claims 38 and 52 for reciting “polyester terephthalate.” Cancellation of Claim 52 renders the objection moot with respect to this claim. With respect to Claim 38, as the Examiner has noted, “polyester terephthalate” is intended to mean “polyethylene terephthalate.” Accordingly, Claim 38 and paragraph [0056] have been corrected. Support for these corrections is found in paragraph 7 of the specification, which lists a number of polymeric substrates including “polyethylene terephthalate (PET).” Furthermore, because polyethylene terephthalate is itself a type of polyester, it would be obvious to those of ordinary skill in the art that “polyester terephthalate” is a typographical error.

### *II. Rejection of Claims under 35 U.S.C. § 112*

The Examiner has rejected Claims 38, 42 and 46-52 under 35 U.S.C. § 112, first paragraph, as based on a disclosure which is not enabling. Cancellation of Claims 51 and 52 renders the rejection moot with respect to these claims. Applicants respectfully traverse the rejection of Claims 38, 42 and 46-50.

The Examiner appears to assert that the claims must be rewritten to reflect the step of plasma functionalization of the polymer surface. In support of the rejection, the Examiner cites *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). In *Mayhew*, claims directed to a *method* for producing a metal coating were rejected for failing to include a step critical to the

practice of the method. Because the missing step was essential, the claims which failed to recite the step were not supported by an enabling disclosure.

Unlike the claims rejected in *Mayhew*, Claims 38, 42 and 46-50 of the present invention are directed to a *product*. As correctly noted by the Examiner, the present invention discloses methods for functionalizing polymer surfaces involving a plasma treatment step. However, the Examiner has cited no authority for the requirement that claimed products be defined by the methods used to make them. Although product-by-process claims are permissible, Applicants respectfully request that the Examiner more clearly specify the circumstances under which they are required. Applicants believe the existence of such a requirement is unlikely because “even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself.” (MPEP 2113). Therefore, the process limitation which the Examiner would like to add to the claim is not relevant to the patentability of the claim. For this reason, Applicants have declined to amend the claims to add this limitation.

The Examiner has also rejected claims 38, 42 and 46-52 under 35 U.S.C. § 112, second paragraph, as being indefinite. Cancellation of Claims 51 and 52 renders the rejection moot with respect to these claims. With respect to independent Claim 38, the Examiner has suggested that the use of “carbon-containing surface” in the claim’s preamble is confusing because the first element of the claim refers to a “polymer surface.” Applicants believe amended Claim 38, which refers to a “surface treated polymer,” eliminates this confusion. The structure of amended Claim 38 now reflects the structure of independent Claims 39 and 40, which have been allowed.

Finally, the Examiner has also rejected Claims 38 for reciting “acetal,” asserting that this term is an improper Markush member because “acetal” is not a polymer. Claim 38 has been amended to clarify that the material in question is an acetal plastic. Accordingly, Applicants respectfully request that the Examiner’s rejection under 35 U.S.C. § 112 of Claims 38, 42 and 46-50 be withdrawn.

### **III. Rejection of Claims under 35 U.S.C. § 102/§103**

The Examiner has rejected claims 38, 42 and 46-52 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,737,544, issued to McCain *et al.* (hereinafter “McCain”). Cancellation of Claims 51 and 52 renders the rejection moot with respect to these claims. In view of the present amendments, Applicants respectfully traverse the rejection of Claims 38, 42 and 46-50.

In order to establish a *prima facie* case of anticipation, a cited reference must teach each and every limitation of the rejected claims. (MPEP 2131.)

McCain does not teach each and every limitation of independent Claim 38. As amended, Claim 38 recites a polymer surface “wherein the polymer is selected from the group consisting of polyethylene, polypropylene, polyethylene terephthalate, and polytetrafluoroethylene” and spacer chains formed from molecules “selected from the group consisting of epichlorohydrin, epibromohydrin, epifluorohydrin and combinations thereof.” McCain discloses biospecific polymers comprising a polymer substrate surface, a spacer molecule and a biomolecule. (See col. 3, lines 27-42.) According to the Examiner, the polymer substrate may comprise methacrylate, carbonate and styrene polymers. (See col. 5, lines 15-16, 26 and 32.) The spacer molecule may be 1,4-butanediol diglycidyl ether. (See col. 9, lines 49-51.) However, McCain does not teach any of the polymers or molecules recited in amended Claim 38. Because McCain fails to teach each and every limitation of independent Claim 38, Applicants respectfully request that the anticipation rejection be withdrawn.

In the alternative, the Examiner rejected these claims under 35 U.S.C. § 103(a) as being obvious over McCain. In support of this rejection, the Examiner stated:

McCain suggests materials for the polymer substrate include all polymers and copolymers that are ‘nontoxic for animal including human, use’ (col. 5, lines 37-40). Therefore, one having ordinary skill in the art would have found it obvious to select the claimed polymeric materials for the polymeric substrate in the product of McCain because such polymeric materials fit the non-toxic condition as recommended by McCain.

In order to establish a *prima facie* case of obviousness, three criteria must be met: (1) the cited reference must provide some motivation to modify the reference's teachings; (2) there must be a reasonable expectation of success; and (3) the resulting modification must teach or suggest all of the limitations of the rejected claims. (MPEP 2142.) In evaluating the teachings of the prior art, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. (MPEP 2141.02 VI.) In addition, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. (MPEP 2143.01 V.)

When considered in their entirety, the teachings of McCain lead away from the replacement of the polymer substrates disclosed therein with the particular polymers recited in Claim 38 of the present invention. McCain discloses conventional wet chemistry methods for producing its biospecific polymers. (See col. 6, lines 58-60.) To form the biospecific polymers, biomolecules and spacer molecules are immobilized on polymer substrates via "spontaneous attachment," "chemical activation of terminal functional groups" on the polymer substrates or "coupling reagent attachment." (See col. 6, lines 63-67 and col. 8, lines 57-61.) Each of these methods requires that the polymer substrate comprise reactive groups (e.g., aldehyde, epoxy, hydroxyl or amine groups). (See col. 6, line 67 – col. 7, line 5; col. 7 lines 21-26; col. 7, lines 47-51.) These biospecific polymers are intended for use in a therapeutic regimen in which a patient's blood, plasma or other body fluid is exposed to the biospecific polymer. (See col. 10, lines 17-27 and lines 47-49.) Immobilized biomolecules on the polymer react with pathogens or other unwanted body fluid components, effectively removing them from the patient's fluids.

As described throughout the specification of the present invention, "inert polymeric substrates (e.g., polyethylene, polypropylene, polyethylene terephthalate (PET), and polytetrafluoroethylene (PTFE))...cannot be functionalized efficiently by using conventional wet chemistry approaches." (See paragraphs 7, 8, 9 and 56). Furthermore, none of the polymers recited in Claim 38 comprise any of the reactive groups taught by McCain. As one of ordinary skill in the art would recognize, because these inert polymers are chemically unreactive, they are

not suited for the functionalization methods and biospecific polymers taught by McCain. Even if McCain suggests substitution of its polymer substrates with other *non-toxic* polymer substrates, the Examiner has identified no motivation for substitution with *inert* polymer substrates which lack the functional groups needed to carry out the chemical attachment methods disclosed by McCain. Indeed, there can be no such motivation because the use of inert polymer substrates would render the biospecific polymers of McCain unsatisfactory for their intended purpose as pathogen removers. Furthermore, in light of the fundamental incompatibility of inert polymer substrates with the wet chemical methods of McCain, such a substitution cannot be based on a reasonable expectation of success.

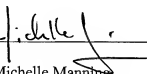
Finally, even assuming modification of McCain's polymer substrates, because McCain fails to disclose the particular molecules for spacer chain formation recited in Claim 38, the resulting modification fails to disclose all of the limitations of the present invention. Because the three criteria of a *prima facie* case of obviousness have not been met, Applicants respectfully request that this rejection be withdrawn.

In view of the foregoing remarks, Applicants respectfully submit that all of the claims remaining in the application are in condition for allowance and favorable action thereon is respectfully solicited.

Respectfully submitted,

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